IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. STEPHEN J. POINDEXTER, an individual, and PHARMACIST'S ULTIMATE HEALTH, a corporation, Defendants.	CIVIL NO. 12-2814 (DSD/AJB)

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys having filed its Complaint for Permanent Injunction against Stephen J. Poindexter, an individual, and Pharmacist's Ultimate Health, a corporation (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Decree without contest, without admitting or denying the allegations of the Complaint and disclaiming any liability in connection herewith, before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399d (the "Act").

3. The complaint alleges that Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

4. The complaint alleges that Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

5. The complaint alleges that Defendants violate 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

6. The complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce dietary

supplements, as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, and held under conditions that do not meet current good manufacturing practice regulations for dietary supplements ("Dietary Supplement cGMP"). 21 C.F.R. Part 111.

7. The complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

8. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons"), are permanently restrained and enjoined under 21 U.S.C. § 332(a) from introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce any drug or dietary supplement unless and until:

A. Defendants have removed all claims from their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media

that cause that product to be a drug within the meaning of the Act;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Labeling Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants and their families or affiliates, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for each of their products on all labels, labeling, promotional materials, and any internet websites owned or controlled by or related to Defendants including, but not limited to, www.puhcorp.com and www.doc-nt.com. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert as soon as they retain such expert. At the conclusion of the Labeling Expert's review, the Labeling Expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants have omitted all claims that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. 321(g), from: (1) each of their product labels, labeling, and promotional materials; (2) websites owned or controlled by or related to Defendants; (3) any other media; and (4) from any and all dietary supplement or cosmetic products under Defendants'

custody, possession, or control. The report shall include the specific results of the Labeling Expert's review, including references to product names and regulations addressed in the process of conducting the review, and copies of the actual labeling that Defendants propose to use on the products. The report shall also include copies of all materials reviewed by the Labeling Expert. The Labeling Expert shall submit this report concurrently to Defendants and FDA no later than twenty (20) calendar days after completing this review;

C. Defendants retain, at Defendants' expense, an independent person or persons (the "Dietary Supplement cGMP Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their families, and who by reason of background, experience, education, and training is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with dietary supplement cGMP, 21 C.F.R. Part 111. Defendants, if appropriate, may retain as the Dietary Supplement cGMP Expert the same independent party they retained as the Labeling Expert. Defendants shall notify FDA in writing of the identity and qualifications of the Dietary Supplement cGMP Expert as soon as they retain such expert;

D. The Dietary Supplement cGMP Expert shall perform a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements, and certify in writing to FDA that (1) he or she has inspected Defendants' facility, methods, processes, and controls; and (2) whether Defendants' operations are, in the Dietary Supplement cGMP Expert's opinion, in compliance with 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111, and this Decree. The Dietary Supplement cGMP Expert's report of the inspection shall be submitted concurrently to Defendants and FDA no later than twenty (20) calendar days after he or she completes the inspection. This report shall include, but not be limited to, the following:

(1) A determination as to whether Defendants have established specifications, as required by 21 C.F.R. § 111.70, and whether those specifications are continuously met as required by 21 C.F.R. §§ 111.73 & 111.80(d);

(2) A determination as to whether Defendants adequately determine and document that products they receive from their suppliers meet specifications, as required by 21 C.F.R. § 111.75;

(3) An evaluation as to whether Defendants' procedures adequately ensure rejection of any product received that does not meet established specifications, as required by 21 C.F.R. § l11.77(c);

(4) A determination as to whether Defendants continuously comply with the procedures and requirements for quality control operations for packaging and labeling, as required by 21 C.F.R. §§ 111.127, 111.165, 111.403 & 111.415;

(5) A determination as to whether Defendants prepare and continuously follow a written master manufacturing record ("MMR") for each unique formulation of each product manufactured and for each batch size, as required by 21 C.F.R. § 111.205(a), and whether Defendants include all required information in the master manufacturing record, as required by 21 C.F.R. § 111.210;

(6) An evaluation as to whether Defendants continuously comply with the regulations regarding batch records and batch production, as specified in 21 C.F.R. §§ 111.255 & 111.260;

(7) A determination as to whether Defendants establish and continuously follow written procedures specifying the responsibilities of their quality control operations, as required by 21 C.F.R. § 111.103;

(8) A determination as to whether Defendants establish and continuously follow written procedures fulfilling the requirements regarding product complaints set forth in 21 C.F.R. §§ 111.560 & 111.570, as required by 21 C.F.R. § 111.553; and

(9) A determination as to whether the dietary supplement products in Defendants' custody, possession, or control were manufactured according to cGMP and 21 C.F.R. Part 111. To support this certification, the Dietary Supplement cGMP Expert shall submit: (a) a MMR for each unique formulation of dietary supplement; (b) batch production records for every batch produced; and (c) laboratory records, including, but not limited to, testing records for incoming raw material, testing records for in-process specifications, and testing records for finished product specifications.

E. Should the Labeling Expert or Dietary Supplement cGMP Expert (collectively, "Experts") identify any deficiencies in their reports as described in Paragraphs 8(B) and 8(D):

(1) Defendants shall report to FDA and the Experts in writing the actions they have taken to correct all such deficiencies; and

(2) The Experts shall certify in writing to FDA whether, based upon the Experts' further review and/or inspection(s), Defendants' facility and their methods, processes, and controls used to manufacture, prepare, pack, label, hold, distribute, and

promote their dietary supplement products appear to be in compliance with the Act, its implementing regulations, and this Decree, and whether Defendants have omitted all claims from each of their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that cause any of the Defendants' products drugs within the meaning of the Act;

F. FDA representatives inspect Defendants' facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree. Such inspection shall commence within thirty (30) business days after receiving Defendants' Experts' complete reports required by Paragraphs 8(B) and 8(D) and any other materials FDA requires to evaluate Defendants' operations; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 8(A) - (F). FDA shall provide such notification within thirty (30) business days of the close of the FDA inspection specified in Paragraph 8(F). In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Paragraph 8 shall not apply if Defendants have in effect an approved new drug application or abbreviated new drug

application filed pursuant to 21 U.S.C. §§ 355(b) or (j), and/or an investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) for all of their products, and Defendants comply with current good manufacturing practices for drugs. See 21 C.F.R. Parts 210 and 211.

10. After Defendants have complied with Paragraphs 8(A)-(F) and received FDA's written notification pursuant to Paragraph 8(G), Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraphs 8(B) and 8(C) to conduct audit inspections of Defendants' facility no less frequently than once every six (6) months for a period of no less than five (5) years (hereinafter, the "Auditor"). The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to Paragraph 8(G). If Defendants choose, the Auditor may be the same person or persons retained as the Labeling Expert or Dietary Supplement cGMP Expert described in Paragraphs 8(B)-(C).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with Dietary Supplement cGMP for their dietary supplement operations and identifying any deviations from such requirements ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor: (a) has personally reviewed all of Defendants' product labels, labeling, promotional materials, and websites; and (b) personally certifies whether the product labels, labeling, promotional materials, and internet websites strictly comply with the requirements of the Act, its regulations, and this Decree.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the Audit Inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' drugs and/or dietary supplements are not in compliance with the Act, its implementing regulations, and/or this Decree, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants

believe that correction of the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

11. Upon entry of this Decree, Defendants and their Associated Persons are permanently restrained and enjoined from

directly or indirectly doing or causing any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), or dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); or

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) or by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

12. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, promotional materials, or websites owned or controlled by or related to Defendants, a report prepared by Defendants' Experts or the

Auditor, or any other information, that that Defendants have failed to comply with any provision of this Decree, have violated the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, and/or this Decree, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, promoting, and/or distributing any or all drugs and/or dietary supplements;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

C. Submit additional reports or information to FDA as requested;

D. Pay liquidated damages as provided in Paragraph 20 below;

E. Recall any article(s) at Defendants' expense; or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and/or this Decree.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

13. Upon receipt of any order issued by FDA pursuant to Paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other actions described in Paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations.

Defendants' written request to resume operations shall include a complete report from Defendants' Auditor which certifies that, in the Auditor's view, Defendants have corrected all violations that caused FDA to issue its order under Paragraph 12 and are otherwise in compliance with the Act, its implementing regulations, and the Decree. FDA will promptly determine whether it needs to conduct an inspection to evaluate Defendants' compliance with the law and this Decree. If FDA determines that an inspection is necessary, it will commence its inspection within thirty (30) business days after receiving Defendants' written request to resume operations. Within forty five (45) business days following the close of the inspection, FDA will determine whether Defendants appear to be in compliance

with this Decree, the Act, and its implementing regulations and, if so, will send Defendants a written notification permitting resumption of operations. If FDA determines that no inspection is necessary, FDA will notify Defendants within thirty (30) business days after receipt of Defendants' request whether Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations and, if so, will send Defendants a written notification permitting resumption of operations. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraphs 12 and 13 shall be borne by Defendants at the rates specified in Paragraph 16.

14. Within ten (10) calendar days after FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any websites owned and controlled by or related to Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in Paragraph 19.

15. FDA representatives shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted immediate

access to buildings, equipment, in-process and finished materials, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, promoting, holding, and distribution of any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. For the purposes of this Decree, inspections include FDA's review and analysis of Defendants' claims contained in product labels, labeling, promotional materials, and any and all websites owned or controlled by or related to Defendants. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these

rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.555 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

17. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of his Associated Persons, and post the Decree on all websites under Defendants' control. Within thirty (30) calendar days after the entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Decree and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall: (a) within fifteen (15)

calendar days of such association, provide a copy of this Decree to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

18. Defendants shall notify FDA, in writing, at the address specified in Paragraph 19, at least fifteen (15) calendar days before: (A) any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation; (B) the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities; (C) any other change in the corporate structure of Pharmacist's Ultimate Health; or, (D) any other change in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

19. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, Minneapolis District

Office, United States Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota, 55401.

20. If Defendants fail to comply with the Act, its implementing regulations, and/or any provision of this Decree, including any time frame imposed by this Decree, Defendants shall pay to the United States of America: (a) two thousand five hundred dollars ($2,500) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; (b) an additional one thousand dollars ($1,000) in liquidated damages per day, per violation, for each violation of the Act, its implementing regulations, and/or this Decree; and (c) an additional sum in liquidated damages equal to twice the retail value of any distributed drugs or dietary supplements that are adulterated, misbranded, or otherwise in violation of the Act, its implementing regulations, and/or this Decree. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

21. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such

contempt proceedings.

22. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

23. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED.

Dated: November 6, 2012.

s/David S. Doty
DAVID S. DOTY, JUDGE
UNITED STATES DISTRICT COURT

Entry consented to by:

FOR DEFENDANTS

s/Stephen J. Poindexter___
STEPHEN J. POINDEXTER,
individually and on behalf of
PHARMACIST'S ULTIMATE HEALTH
CORP.

_s/Justin J. Prochnow_____
JUSTIN J. PROCHNOW
Greenberg Traurig, LLP
1200 17th Street, Suite 2400
Denver, Colorado 80202
(303) 572-6562

Attorney for STEPHEN J.
POINDEXTER and PHARMACIST'S
ULTIMATE HEALTH CORP.

FOR PLAINTIFF

B. TODD JONES
United States Attorney

s/Ann M. Bildtsen_____
ANN M. BILDTSEN
Assistant U.S. Attorney
600 U.S. Courthouse
300 South 4th Street
Minneapolis, MN 55415
(612)-664-5615

s/Timothy T. Finley_____
TIMOTHY T. FINLEY
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
(202) 307-0050

OF COUNSEL:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel,
Litigation

SONIA W. NATH
Associate Chief Counsel for
Enforcement
United States Department of
Health and Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002